4.1 Summary of Safety and Effectiveness

Air Safety Ltd.
NFC House, Vickers Industrial Estate
Mellishaw Lane
Morecambe, Lancs LA3 3EN
England

Non-Confidential Summary of Safety and Effectiveness

14-Apr-05

Official Contact:	Steve Brown – Quality Manager
Proprietary or Trade Name:	Air Safety Model 3000/06 HEPA Filters
Common/Usual Name:	Bacterial / Viral Filters
Classification Name:	Filter, Bacterial, Breathing Circuit, CAH
Predicate Devices:	Air Safety – Model 3000/04 – K033008 PB Omniflow Filter – K890362

Device Description

The Air Safety Model 3000/06 HEPA filter is a multi-use, reusable ventilator in-line filter which connects in the exhaust side of the PB 700 series and 7200 ventilators. It can be cleaned by steam autoclave up to 100 times or 1 year service life. It has standard 22 mm tubing connectors and it has a clear housing. It contains the Air Safety standard Multipleat media which has been HEPA tested for rating performance according to BS 3928 Sodium Flame for Air filters and in accordance to DOE 3202-97 and ASTM D2986 – DOP. In addition BFE and VFE testing has been performed by Nelson Laboratories to demonstrate substantial equivalence to the predicate devices.

Intended Use and Environments

Filtration of exhaled gases in the ventilator circuit.

Model 3000/06 to be placed in the exhalation pathway of the ventilator circuit where filtration of the expired gases is desired. Filter is reusable up to 100 times, extended use as determined by the increase in airflow resistance, which is determined during self testing (SST) mode of the ventilator. For use with the Series 700 and 7200 NPB ventilators.

Cleaning method – autoclaved – 30 minutes with 3 minutes at 134°C.

Environment of Use -- Hospital, Sub-acute Institutions

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General Technical Characteristics

Attribute	Air Safety Model 3000/04 – K033008 PB – Omniflow – K890362
Indications for use - To filter expired gases.	Same
Intended for extended use up to 15 days continuous, reusable up to 100 times via autoclave or 1 year service life	Yes
Prescription	Yes
Intended population	Any patient on a ventilator – PB 700 series and 7200
Intended Environment of Use	Hospital, sub-acute institution
Placement in exhalation limb of circuit	Yes
Design	
Reusable housing and materials	Yes
Clean by autoclave	Yes
Standard 15/22 mm connectors	Yes
Dead Space (ml)	~ 350 ml
Resistance to flow	$\leq$ 1.5 cm H_2O at 60 lpm and $\leq$ 2.5 cm H_2O at 100 lpm
HEPA - Bacterial filtration – BFE – Nelson Lab.	99.999%
HEPA - Viral filtration – VFE – Nelson Lab.	99.999%
Materials	
Housing polycarbonate	Yes
Filter media - HEPA	Paper fiber
Performance Standards	
None under Section 514	Yes
ISO 5356-1 Conical 15/22	Yes
DOE 3202-97 and ASTM D2986 - DOP	Yes > 99.97% of 0.3 micron DOP particle

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed devices when compared to the predicate devices are safe and effective and are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

Mr. Paul Dryden
President
Air Safety Ltd.
c/o ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055-9501

Re: K050953
Trade/Device Name: Air Safety Model 3000/06 HEPA Filters
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: April 14, 2005
Received: April 18, 2005

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.3 Indications for Use

510(k) Number: K050953 (To be assigned)

Device Name: Air Safety Model 3000/06 HEPA Reusable filter

Intended Use:

Filtration of exhaled gases in the ventilator circuit.

Model 3000/06 to be placed in the exhalation pathway of the ventilator circuit where filtration of the expired gases is desired. Filter is reusable up to 100 times, extended use as determined by the increase in airflow resistance, which is determined during self testing (SST) mode of the ventilator. For use with the Series 700 and 7200 NPB ventilators.

Cleaning method – autoclaved – 30 minutes with 3 minutes at 134°C.

Environment of Use -- Hospital, Sub-acute Institutions

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-the-counter use** __

(Per CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050953